

December 5, 1999

The Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

9190 '99 DEC 21 P1:58

Re: 21 CFR Parts 210, 211, 820, and 1271
Suitability Determination for Donors of Cellular & Tissue-Based Products

To Who It May Concern:

As a member of the **Deerfield** Beach Lions Club and, one of the 150 Lions Clubs in South Florida consisting of more than 6,000 men and women, I am writing to express my opposition to the proposed Food and Drug Administration's rule to require a donor medical history interview for all **corneal** donors. I am proud of the fact that the Florida Lions Eye Bank has, over the past 38 years, **provided** more than 32,000 corneas to patients totally free of charge. This has **saved** the Medicare program more than **\$1,000,000** each year from our eye **bank** alone.

The FDA's effort to address transmission of **Creutzfeldt** Jacob Disease (CJD) will eliminate the most successful eye bank program in the nation. While the motive is admirable, the new requirement will not serve that purpose. Our medical advisors state that additional next of kin screening requirements will not add to the safety of **corneal** tissue for CJD. This has been well demonstrated 32,000 times **over** the past 38 years.

As you must know, patients who **have** the symptoms **for** CJD usually die in hospitals and are of advanced age (over 60). The Florida Lions Eye Bank's Medical Examiner's program obtains corneas from those who die in a sudden accidental death. The ages typically range from **20-40** years of age. This is not a high risk group. Also, those who die a sudden death from other causes, but who might **have** the disease in the latent stage, would not exhibit any symptoms of CJD..thus asking **even** hundreds of question regarding behavior, etc. would **serve** no purpose.

Each day here in South Florida many new patients are added to the waiting list **for corneal** transplantation. Unnecessary screening will further delay the wait time and extend the suffering and impaired vision of many men, women, and children. In addition, if the eye bank is forced to hire more employees to try to track down someone to interview on each suitable case at the medical examiners offices, it will become necessary to begin to charge a processing fee. Since the majority of **corneal** recipients are over 65, the **government** will be charged for a **service** provided free **for** 38 years.

Sincerely,



Gary Levin, President
Deer-field Beach Lions Club
1560 N.E. 27th Street
Pompano Beach, Florida 33064

97N-4845

C 167